APR 2 6 2001

K004046

510(k) Summary

SUBMITTER:	COBE Cardiovascular, Inc. 14401 W. 65th Way Arvada, CO 80004
CONTACT PERSON:	Lynne Leonard Phone: (303) 467-6586 Fax: (303) 467-6429
DATE PREPARED:	December 18, 2000
DEVICE TRADE NAMES:	COBE® VVR 4000™ Filtered Hardshell Venous Reservoir COBE® SMARxT® VVR 4000™ Filtered Hardshell Venous Reservoir
COMMON/USUAL NAME:	Filtered Venous Reservoir with Integral Cardiotomy Filter
CLASSIFICATION NAMES:	Cardiopulmonary Bypass Blood Reservoir with Defoamer Cardiotomy Suction Line Blood Filter
PREDICATE DEVICE:	COBE® HVR™ 2200 Filtered Hardshell Venous Reservoir

DEVICE DESCRIPTION:

The COBE® VVR 4000™ and COBE® SMARxT® VVR 4000™ Filtered Hardshell Venous Reservoirs are sealed hardshell venous blood reservoirs with a defoamer and integral cardiotomy filter. The devices are supplied sterile with non-pyrogenic fluid pathways, and are for single use only. They are indicated for use in surgical procedures requiring cardiopulmonary bypass for periods of up to six hours.

The purpose of this premarket submission is to reduce the minimum operating volume specification of the devices from 200 ml to 100 ml at blood flow rates up to 5 liters/minute, and to allow use of the devices on pediatric patients.

STATEMENT OF TECHNICAL CHARACTERISTICS COMPARISON

The COBE® VVR 4000™ and COBE® SMARxT® VVR 4000™ Filtered Hardshell Venous Reservoirs are substantially equivalent to the currently marketed COBE® HVR™ 2200 Filtered Hardshell Venous Reservoir (K994389). The devices have the same intended use, design, materials, and construction, with the following primary differences:

The COBE® VVR 4000™ and COBE® SMARxT® VVR 4000™ Filtered Hardshell Venous Reservoirs are sealed to allow a vacuum to be applied during vacuum assisted venous drainage (VAVD). The reservoirs have an integral pressure relief valve and vent port to prevent implosion and excessive pressurization.
The COBE® VVR 4000™ and COBE® SMARxT® VVR 4000™ Filtered Hardshell Venous Reservoirs have a reservoir capacity of 4000 ml and a ½" venous inlet. The COBE® HVR™ 2200 has a reservoir capacity of 2200 ml and a 3/8" venous inlet.
The COBE® SMARxT® VVR 4000™ contains a surface-modifying additive that improves the blood compatibility of the device.

In-vitro test data demonstrate that the COBE® VVR 4000™ and COBE® SMARxT® VVR 4000™ Filtered Hardshell Venous Reservoirs are substantially equivalent to the COBE® HVR™ 2200 Filtered Hardshell Venous Reservoir.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 6 2001

Lynne Leonard
Sr. Regulatory and Clinical Affairs Manager
COBE Cardiovascular, Inc.
14401 West 65th Way
Arvada, CO 80004-3599

Re: K004046
Trade Name: COBE® VVR 4000™ and SMARxT® VVR 4000™ Filtered Hardshell Venous Reservoirs
Regulatory Class: III (three)
Product Code: DTP/DTN
Dated: April 5, 2001
Received: April 06, 2001

Dear Ms. Leonard:

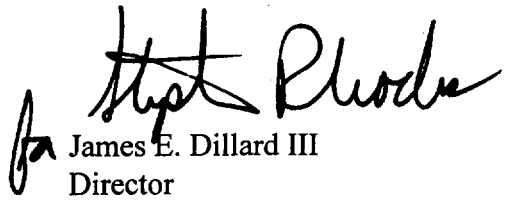
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications For Use

510(k) Number (If known): K004046

Device Names: COBE® VVR 4000™ Filtered Hardshell Venous Reservoir
COBE® SMARxT® VVR 4000™ Filtered Hardshell Venous Reservoir

Indications For Use:

The COBE® VVR 4000™ and SMARxT® VVR 4000™ Filtered Hardshell Venous Reservoirs are intended to be used in surgical procedures requiring cardiopulmonary bypass for periods of up to six hours.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K004046

Prescription Use Y OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

3/27/1

Division of Cardiovascular & Respiratory Devices
510(k) Number K004046